MAR 1 3 2014

510(K) SUMMARY	
Date Summary Prepared	November 1, 2013
Manufacturer/Distributor/Sponsor	OMNIlife Science 50 O'Connell Way Suite 10 East Taunton, MA 02718
510(k) Contact	Christina Flores Manager, Regulatory Affairs Omnilife Science 50 O'Connell Way East Taunton, MA 02718 Telephone: 774-226-1835 Fax: 508-822-6030 Email: cflores@omnils.com
Trade Name	OMNI ARC Monoblock Hip Stem
Common Name	prosthesis, hip, semi-constrained, metal/polymer, porous uncemented prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium-phosphate
Classification Name	21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis. LZO, MEH, LPH, KWY
Predicate Device	K113242 - Apex Hip System ARC™ Hip Stem *(cleared size 0)* K110947 - Apex K1™ Hip Stem Reference predicates: K111193 Apex Hip System ARC™ Hip Stem (cleared size 1-5) K060072 Apex K1 Hip Stem(cleared size 2-12)
Purpose of Submission	This Traditional 510(k) premarket notification is being submitted to obtain clearance for the OMNI ARC Monoblock Hip Stem to expand OMNI's product offering for total hip arthroplasty.

510(K) SUMMARY	
Device Description and intended use	The OMNI ARC Monoblock Hip Stem consists of a curved, rectangular tapered stem that combines the neck and stem into a single piece design. The OMNI ARC Monoblock Hip Stem is intended for use as the femoral component of a primary or revision total hip replacement when used with the Apex Interface Acetabular System. The Apex Interface Acetabular System articulates with the Apex Modular Femoral Head (Cobalt Chromium or Ceramic). The femoral hip stem is intended for uncemented fixation and single use implantation. These prostheses may be used for hip arthroplasty to treat the following conditions, as appropriate: • Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis; • Rheumatoid arthritis; • Correction of functional deformity; • Congenital dislocation; • Revision procedures where other treatments or devices have failed; • Femoral neck and trochanteric fractures of the proximal femur. The OMNI ARC™ Monoblock Hip Stem is also intended for use in hemiarthroplasty when used with the Apex Bipolar Head. The Apex Hip System Bipolar Head is intended for use in combination with an Apex Hip System femoral stem for uncemented primary or revision hemiarthroplasty of the hip. This prosthesis may be used for the following conditions, as appropriate: • Femoral neck and trochanteric fractures of the proximal femur; • Osteonecrosis of the femoral head; Revision procedures where other treatments or devices for these indications have failed.

510(K) SUMMARY	
Substantial Equivalence Summary	The OMNI ARC Monoblock Hip Stem is substantially equivalent to the predicate APEX ARC Hip Stem (K113242) and the Apex K1 Hip Stem (K110947) in which the fundamental scientific technology and intended uses are the same. Any differences between the OMNI ARC Monoblock Hip Stem and the predicates are considered minor and do not raise questions concerning safety and effectiveness. The proposed devices are composed of titanium alloy, unalloyed titanium plasma spray, with hydroxyapatite coating, the identical material used in the manufacture of the predicate devices. The results of testing of the proposed ARC Monoblock Hip Stems met the requirements for fatigue strength per ISO 7206-6 and ISO 7206-4 and the range-of-motion requirement per ISO 21535. These test methods are the same used for the predicate devices (K110947 and K113242). Based on the indications for use, technological characteristics, and the comparison to the predicate devices, OMNIlife Science has determined that the OMNI ARC Monoblock Hip Stem is substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 13, 2014

OMNIlife Science
Ms. Christina Flores
Manager, Regulatory Affairs
50 O'Connell Way, Suite 10
East Taunton, Massachusetts 02718

Re: K133381
Trade/Device Name: OMNI ARC Monoblock Hip Stem
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, MEH, LPH, KWY
Dated: February 6, 2014
Received: February 10, 2014

Dear Ms. Flores:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Not Known K133381

Device Name: OMNI ARC Monoblock Hip Stem

The OMNI ARC Monoblock Hip Stem is intended for use as the femoral component of a primary or revision total hip replacement when used with the Apex Interface™ Acetabular System. The Apex Interface™ Acetabular System articulates with the Apex Modular Femoral Head (Cobalt Chromium or Ceramic). The femoral hip stem is intended for uncemented fixation and single use implantation. These prostheses may be used for hip arthroplasty to treat the following conditions, as appropriate:

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Congenital dislocation;
- Revision procedures where other treatments or devices have failed;
- Femoral neck and trochanteric fractures of the proximal femur.

The OMNI ARC Monoblock Hip Stem is also intended for use in hemiarthroplasty when used with the Apex Bipolar Head.

The Apex Hip System Bipolar Head is intended for use in combination with an Apex Hip System femoral stem for uncemented primary or revision hemiarthroplasty of the hip. This prosthesis may be used for the following conditions, as appropriate:

- Femoral neck and trochanteric fractures of the proximal femur;
- Osteonecrosis of the femoral head;
- Revision procedures where other treatments or devices for these indications have failed.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S